

KSC/04.05.21
JDM: USAO#2017R00712**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND****UNITED STATES OF AMERICA****v.****HOWARD HOFFBERG,****Defendant.****CRIMINAL NO. RDB 21-cr-178****(Conspiracy to Violate Anti-Kickback
Statutes, 18 U.S.C. § 371; Forfeiture)****INFORMATION****COUNT 1****(Conspiracy to Violate Anti-Kickback Statutes)**

The United States Attorney for the District of Maryland charges that:

1. From June 2012 to in or about January 2018, in the District of Maryland:

The Defendant

a. The Defendant, Howard Hoffberg, was a doctor who was licensed to practice medicine in Maryland.

b. The Defendant served as the Associate Medical Director and part-owner of Rosen-Hoffberg Rehabilitation and Pain Management (the "Practice"). The Practice's Medical Director was Norman Rosen. The Defendant principally worked at the Practice's location at 10085 Red Run Boulevard, Owings Mills, MD 21117, but at times also worked at the Practice's locations in Towson, Maryland.

The Medicare Program

c. The Medicare Program ("Medicare") was a federally-funded health care program providing benefits to people who were 65 years of age or older, or who were disabled. Medicare was administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency

within the U.S. Department of Health and Human Services (“HHS”). Individuals who received Medicare benefits were referred to as Medicare “beneficiaries.”

d. Medicare was a “Federal health care program” as defined in 42 U.S.C. § 1320a-7b(f), and a “health care benefit program” as defined in 18 U.S.C. § 24(b).

e. Medicare was divided into four parts: hospital insurance (Part A), medical insurance (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D).

f. CMS contracted with drug plan sponsors to administer the Medicare Part D program and provide prescription drug benefits to Medicare beneficiaries. The plan sponsors decided which drugs they covered and how much they would pay for those medications. CMS, through the federal treasury, reimbursed the Part D plan sponsors for the covered drugs.

g. In order for Medicare to pay for medications, they had to be prescribed by a physician. Physicians could enroll as Medicare providers. To enroll in Medicare, providers had to agree to abide by all provisions of the Social Security Act, the regulations promulgated under the Act, and applicable policies, procedures, rules, and regulations issued by CMS and its authorized agents and contractors.

h. Medicare regulations required health care providers enrolled with Medicare to maintain complete and accurate patient medical records reflecting the medical assessment and diagnoses of their patients, as well as records documenting actual treatment of the patients to whom services were provided.

i. Medicare paid for claims only if the services were medically reasonable and necessary. Medicare would not pay for medications if the prescriptions were written in exchange for a bribe or kickback.

Insys and Subsys

j. Insys Therapeutics, Inc. (“Insys”) was a company incorporated in Delaware and headquartered in Arizona.

k. In or around January 2012, the U.S. Food and Drug Administration (“FDA”) approved Insys’s application to sell and market a drug (hereinafter, “Subsys”) to patients suffering from cancer who were experiencing breakthrough pain. Breakthrough pain is a sudden, short-term increase in pain that may occur in patients who have chronic pain from cancer and whose pain is not controlled by their normal medication regime.

l. Subsys was a potent opioid designed to rapidly enter a patient’s bloodstream upon being sprayed under the tongue. Subsys contained fentanyl, which is a synthetic opioid pain reliever that was classified as a Schedule II controlled substance under the Controlled Substances Act, meaning that it has a high potential for abuse and can lead to physical dependence. Fentanyl is approximately 50 to 100 times more potent than morphine.

m. The FDA approved Subsys solely for the “management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

n. Subsys was in a category of drugs known as Transmucosal Immediate Release Fentanyl (“TIRF”). Because of the risk of misuse, abuse, addiction, and overdose associated with TIRF drugs, including Subsys, only practitioners enrolled in the FDA-mandated TIRF Risk Evaluation and Mitigation Strategy program (the “TIRF REMS Program”) were allowed to prescribe TIRF drugs. Practitioners were required to complete training and testing to enroll in the TIRF REMS Program.

o. Insys manufactured and sold Subsys in dosage strengths of 100, 200, 400, 600, 800, 1,200, and 1,600 micrograms.

p. Subsys was expensive and profitable for Insys. The approximate average retail cost of a one-month supply of four daily doses of Subsys at 100 micrograms was approximately \$3,000. Higher dosage strengths were more expensive. The approximate average retail cost of a one-month supply of four daily doses of Subsys at 800 micrograms was approximately \$15,000.

The Conspiracy

2. From in or around June 2012 through in or around January 2018, in the District of Maryland and elsewhere, defendant

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did willfully and knowingly, combine, conspire, confederate, and agree with others known and unknown to the Grand Jury, to commit certain offenses against the United States, namely:

a. to defraud the United States and any of its agencies out of money and property, and by impairing, impeding, obstructing, and defeating through deceitful and dishonest means the lawful government functions of HHS in its administration and oversight of Medicare, and the lawful government functions of the FDA in its administration and oversight of the TIRF REMS Program;

b. to violate Title 42, United States Code, Section 1320a-7b(b)(1)(B), by knowingly and willfully soliciting and receiving remuneration, specifically, kickbacks and bribes, directly and indirectly, overtly and covertly, in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

Object of the Conspiracy

3. It was the object of the conspiracy for the Defendant and his co-conspirators to unlawfully enrich themselves by, among other things: (a) offering, paying, soliciting, and receiving kickbacks and bribes in exchange for prescribing Subsys; (b) submitting and causing the submission of false and fraudulent claims to Medicare and private insurance companies for prescription drugs that were ineligible for reimbursement; and (c) diverting proceeds of the fraud for the personal use and benefit of the Defendant and his co-conspirators.

Manner and Means of the Conspiracy

4. The manner and means by which the Defendant and his co-conspirators sought to accomplish the purpose of the conspiracy included, among others, the following:

a. The Defendant applied for and maintained various Medicare, U.S. Drug Enforcement Administration, TIRF REMS, and other provider numbers associated with the Defendant personally, and the Practice.

b. In or around September 2011, the Defendant certified to Medicare that he would comply with all Medicare rules and regulations, including that he would not present or cause to be presented a false or fraudulent claim for payment by Medicare and that he would refrain from violating the federal anti-kickback statutes.

c. In or around August 2013, and again in August 2015, and again in June 2017, the Defendant certified to the FDA that he would assess patients to whom he prescribed TIRF drugs, including Subsys, “for appropriateness of the dose” of the TIRF drug, and “for signs of misuse and abuse” at “all follow-up visits.” The Defendant also certified that he understood that TIRF drugs, including Subsys, were “indicated only for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around-the-clock opioid

therapy for their underlying persistent pain,” and that “an increased risk of misuse, abuse, or overdose” of TIRF drugs “should be considered” before prescribing. The Defendant also certified that he understood that TIRF drugs were “contraindicated” for use in patients who were not opioid tolerant. The Defendant also certified that the initial starting dose of any TIRF drug for all patients was the lowest dose possible (100 mcg), unless otherwise indicated on the product labels. Finally, the Defendant certified that it would be improper to convert patients from one TIRF drug to another TIRF drug on a microgram-by-microgram basis.

d. Due to the limited number of patients suffering from breakthrough cancer pain, Insys, by and through its officers, managers, and employees, designed and implemented an illegal kickback and bribery scheme to induce the Defendant and others to prescribe Subsys for pain caused by conditions other than breakthrough cancer pain.

e. In order to conceal and disguise that kickbacks and bribes were being paid to induce the Defendant and other doctors to prescribe Subsys, Insys falsely designated the payments to the Defendant and others as “honoraria” for purportedly providing educational presentations regarding Subsys through Insys’s Speaker Bureau Programs.

f. In or around June 2012, and again in October 2015, the Defendant entered into written agreements with Insys where he agreed to be paid through the Speaker Bureau Program. In doing so, the Defendant falsely represented that the Speaker Bureau Program honoraria he received from Insys would not affect his decisions about prescribing Subsys.

g. The Defendant solicited and received more than \$66,000 in illegal kickbacks and bribes from Insys for purportedly providing Speaker Bureau Program presentations.

h. In exchange for the kickbacks and bribes, the Defendant prescribed over 400 prescriptions for Subsys, for a total morphine milligram equivalent (“MME”) of 5,484,960.

Some of these prescriptions were written for patients who did not have cancer diagnoses. In some instances, the Defendant switched patients from one TIRF drug to Subsys based on his receipt of payments from Insys.

i. The Defendant, employees of Insys, and others concealed and disguised that the Defendant's participation in Speaker Bureau Program for Insys was a sham: the presentations lacked the appropriate audience of licensed practitioners seeking educational information regarding Subsys; and/or the same attendees attended the same presentation over and over again; and/or the event was cancelled but the Defendant was still paid.

j. The Defendant caused Medicare to pay for Subsys prescriptions that were procured by the payment of kickbacks and bribes and/or not eligible for Medicare reimbursement.

Overt Acts in Furtherance of the Conspiracy

5. In furtherance of the conspiracy, and to accomplish its purposes and objects, the Defendant and his co-conspirators committed or caused the commission of the following overt acts, among others, in the District of Maryland and elsewhere:

6. On or about June 20, 2012, and again on or about October 14, 2015, the Defendant signed a Speakers Bureau Program agreement with Insys.

7. On or about June 27, 2013, Insys paid the Defendant \$2,400 under the Speakers Bureau Program even though the scheduled event was cancelled and no presentation was given.

8. On or about April 27, 2015, Insys paid the Defendant \$3,000 under the Speakers Bureau Program even though the scheduled event was cancelled and no presentation was given.

9. The Defendant received the following payments from Insys on the following dates for Speaker Bureau Program presentations that were sparsely attended or cancelled, attended by the

same people who had previously attended other presentations, and/or attended by representatives of Insys and persons associated with the Practice who could not prescribe Subsys and who could not prescribe controlled substances:

a. The Defendant was paid on or about October 3, 2012, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

b. The Defendant was paid on or about October 11, 2012, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

c. The Defendant was paid on or about October 24, 2012, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

d. The Defendant was paid on or about November 16, 2012, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

e. The Defendant was paid on or about January 23, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

f. The Defendant was paid on or about June 27, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

g. The Defendant was paid on or about July 31, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

h. The Defendant was paid on or about August 7, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

i. The Defendant was paid on or about September 18, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

j. The Defendant was paid on or about September 25, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

k. The Defendant was paid on or about October 16, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

l. The Defendant was paid on or about October 24, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

m. The Defendant was paid on or about November 13, 2013, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

n. The Defendant was paid on or about February 17, 2014, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

o. The Defendant was paid on or about July 30, 2014, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

p. The Defendant was paid on or about October 15, 2014, with a check in the amount of \$2,400 in connection with the Speakers Bureau Program;

q. The Defendant was paid on or about October 29, 2014, with a check in the amount of \$3,000 in connection with the Speakers Bureau Program;

r. The Defendant was paid on or about January 14, 2015, with a check in the amount of \$3,000 (Check No. 28746) in connection with the Speakers Bureau Program;

s. The Defendant was paid on or about January 20, 2015, with a check in the amount of \$3,000 (Check No. 29004) in connection with the Speakers Bureau Program;

t. The Defendant was paid on or about February 18, 2015, with a check in the amount of \$3,000 (Check No. 29484) in connection with the Speakers Bureau Program;

u. The Defendant was paid on or about April 21, 2015, with a check in the amount of \$3,000 (Check No. 30748) in connection with the Speakers Bureau Program;

v. The Defendant was paid on or about July 9, 2015, with a check in the amount of \$3,000 (Check No. 32648) in connection with the Speakers Bureau Program;

w. The Defendant was paid on or about July 15, 2015, with a check in the amount of \$3,000 (Check No. 32734) in connection with the Speakers Bureau Program;

x. The Defendant was paid on or about September 29, 2015, with a check in the amount of \$3,000 (Check No. 34128) in connection with the Speakers Bureau Program;

y. The Defendant was paid on or about December 7, 2015, with a check in the amount of \$3,000 (Check No. 35476) in connection with the Speakers Bureau Programs.

10. As a result of his receipt of payments from Insys as described above, the Defendant prescribed Subsys to patients of the Practice, some of whom did not have a cancer diagnosis. Additionally, as a result of his receipt of payments from Insys as described above, the Defendant switched some patients of the Practice from one pharmaceutical company's fentanyl-based TIRF drug to Insys's Subsys product.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE ALLEGATIONS

The United States Attorney further finds that:

1. Pursuant to Rule 32.2, Fed. R. Crim. P., notice is hereby given to the defendant that the United States will seek forfeiture as part of any sentence in accordance with 18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), and 28 U.S.C. § 2461 in the event of the Defendant's conviction under Count 1 of this Information.

2. Pursuant to Title 18, United States Code, Sections 981 and 982, upon conviction of a Federal health care offense, the Defendant,

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shall forfeit to the United States of America: any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

3. If any of the property described above, as a result of any act or omission of the defendant:
- a. cannot be located upon the exercise of due diligence;
 - b. has been transferred or sold to, or deposited with, a third party;
 - c. has been placed beyond the jurisdiction of the court;
 - d. has been substantially diminished in value; or
 - e. has been commingled with other property that cannot be divided without

difficulty;

the United States of America shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c).

18 U.S.C. § 981(a)(1)(C)
18 U.S.C. § 982(a)(7)
28 U.S.C. § 2461(c)
Fed. R. Crim. P. 32.2(a)



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JONATHAN F. LENZNER
ACTING UNITED STATES ATTORNEY